



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1206]

Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.7 Implementation Guide 3.3 and for Define-Extensible Markup Language Version 2.1; Requirement Ends for Study Data Tabulation Model Version 1.3 Implementation Guide 3.1.3; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice correction that appeared in the *Federal Register* of August 20, 2020. The document announced the correction dates that the support and requirement were to begin for version 1.7 of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM), and version 3.3 of the SDTM Implementation Guide (SDTMIG), and for version 2.1 of the Define-Extensible Markup Language (Define-XML). The document erroneously provided the incorrect dates for these electronic study data standards. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993-0002, 301-796-0035, cdcrdatastandards@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of August 20, 2020 (85 FR 51450), in FR Doc. 2020-18236, the following correction is made:

On page 51450, in the second and third columns, the last paragraph of the document is corrected to read as follows: “On page 40659, in the first column, the last three sentences of the

document are corrected to read as follows: Support for version 1.7 of the CDISC SDTM, version 3.3 of the SDTMIG, and version 2.1 of the Define-XML will begin on March 15, 2021, and the date that the requirement begins will be on March 15, 2022, for new drug applications, abbreviated new drug applications, and certain biologics license applications. For certain investigational new drug applications, the date that requirement begins will be March 15, 2023. Support and requirement for version 1.3 of the CDISC SDTM and version 3.1.3 of the SDTMIG will end on March 15, 2021.”

Dated: December 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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